

**REMARKS**

In this paper, claims 2, 6, 8-10, and 16 are cancelled, and new claims 20-30 are added.

Support for the new claims can be found throughout Applicants' specification including the original claims. In particular, support for new claims 20-22 and 28-30 can be found at lines 4 -12, and 21-29 of page 4, examples at page 10 through page 18 of the as-filed specification.

Support for new claim 23 can be found, for example, in claim 2 as originally presented, and by lines 1-4 of page 3, lines 14-18 and 26-28 of page 5, and line 11-14 of page 6 in the as-filed specification. Support for claims 24-27 can be found in original claims 4, 5, 14, and 15, respectively.

Upon the entry of this paper, claims 1, 4, 5, 14, 15, and 17-30 are pending in this application, all of which are for further examination on the merits.

No new matter has been introduced by this paper.

Amendment or cancellation of any claim herein is not to be construed as acquiescence to any of the rejections/objections set forth in the Office Action, and was done solely to expedite prosecution of the application.

Applicants respectfully reserve the right to pursue any non-elected, cancelled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications. Reconsideration of the application is requested in view of the remarks herein.

**Rejection Under 35 USC § 112, First Paragraph**

Claims 1, 2, 4, 5, 14, 15, and 17-19 are rejected in the Office Action under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office asserts that the instant claims fail to recite the use of certain excipients as demonstrated in the examples (see page 3 of the Office Action). Applicants respectfully disagree and hereby traverse.

Nevertheless, without acquiescing in any way to the rejection and solely to expedite prosecution of the application, Applicants respectfully point out that claim 1 and those depending therefrom now recite a step of providing a tablet containing

vardenafil hydrochloride and a disintegrant, and a step of coating the tablet with a coating agent (*see* claim 1 as amended).

Applicants respectfully submit that the instant claims have satisfied the written description requirement. Applicants consider that the claim languages now clearly convey the information that Applicants have invented the subject matter which is now claimed. Applicants further point out that the use of any particular excipients (such as disintegrants and coating agents) is neither essential nor critical to the present invention, and thus that the recitation of any of such particular disintegrants and/or coating agents should not be deemed necessary or required for conveying to one skilled in the art the information with respect to the claimed invention (*see* MPEP 2163).

Applicants further submit that those particularly mentioned excipients (e.g., disintegrants and coating agents) in the examples are conventional in the art. In other words, without reciting any of such particular excipients, one skilled in the art would still immediately envisage and carry out the claimed invention based on the present claim languages. In this regard, Comparative example 1 and part of Example 6 are directed to conventional production methods of making coated tablets, whereas Example 2 and the other part of Example 6 relate to the presently claimed method(s). Clearly, the same excipients (e.g., disintegrants and coating agents) were employed in the methods of these examples (*see* pages 10 and 14 of the as-filed specification). However, despite that these formulation processes used the same excipients, Applicants note that vardenafil hydrochloride is only partially present in the desired trihydrate form in the coated tablets obtained through the conventional methods, while substantially all (i.e., at least 90 mol%) of the vardenafil hydrochloride is present in the desired trihydrate form in the coated tablet obtained through the claimed method(s) (*see*, e.g., Comparative example 1, Examples 2 and 6, and figures 1a and 1b of the specification). Accordingly, Applicants submit that none of those particular excipients used in the formulation process contributes in any way to such major differences in the coated tablets as obtained. Indeed, an essential or key feature of the present invention is the rehydration step, which involves using relatively high humidity (e.g., treating the tablet with a moistened gas), as recited in the presented claims. Therefore, Applicants submit that the instant claims have now clearly and sufficiently convey to a skilled artisan the information with respect to what is deemed to be Applicants' invention.

Moreover, Applicants submit that Applicants' specification clearly indicates that various types of excipients may be used in the present invention (*see*, e.g., discussions at pages 4 and 5 of the specification). Further, in contrast to the Office's understanding, Applicants point out that the examples in the specification are provided just by way of illustration, and should not be deemed to limit the scope of the invention, as Applicants' specification expressly states: "[t]he following examples serve to illustrate the invention further, but the invention is not confined to the examples" (*see* lines 22-23, page 9). As such, Applicants submit that the use of any particular excipients (e.g., disintegrants and coating agents) *is not and should not be deemed essential or critical* to the present invention, and thus it should not be required to be incorporated as a limitation.

Finally, Applicants wish to point out that dependent claims 20-22 are added through this paper. These claims are not presented to acquiesce in any way to the rejection, but only to specifically cover the examples which are deemed illustrative of the invention.

Accordingly, Applicants submit that the pending claims of this application have satisfied the written description requirement. Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is proper and the same is requested.

#### **Rejection Under 35 USC § 112, Second Paragraph**

Claim 2 is rejected under 35 USC § 112, second paragraph, as allegedly indefinite. Specifically, the Office alleges that it is unclear whether the treating step occurs prior to or after the coating step (*see* page 4 of the Office Action). Applicants respectfully disagree and traverse.

Nevertheless, without acquiescing in any way to the rejection and solely to expedite prosecution of the application, Applicants respectfully point out that claim 2 has been cancelled in this paper. Accordingly, the rejection is now moot.

Therefore, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is proper and the same is requested.

**CONCLUSIONS**

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. Should any of the claims not be found to be in condition for allowance, the Examiner is requested to call Applicants' undersigned representative to discuss the application. Applicants thank the Examiner in advance for this courtesy.

It is believed that no fee is required for entry and consideration of this paper. Nevertheless, Applicants authorize the Director to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under the Order No. 83964 (303989).

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Respectfully submitted,

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